MAR 19 2014

510(k) Summary

807.92(c)

SPONSOR **807.92(a)(1)**

Company Name: Advanced Fluidics, LLC

Company Address: 8860 Columbia 100 Parkway, Suite 204
Columbia, MD 21045

Telephone: (443) 864-5295

Contact Person: Surya Raghu, Ph.D.

Summary Preparation Date: June 28, 2013

DEVICE NAME **807.92(a)(2)**

Trade Name: Melys Atrial Fibrillation Monitor
Common/Usual Name: Atrial Fibrillation Monitor
Classification Name: Telephone electrocardiograph transmitter and receiver
Regulation Number: 21 CFR 870.2920
Product Code: DXH
Device Class: Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

K Number	Device	Manufacturer
K052767	AfibAlert Atrial Fibrillation Detector	Lechnologies Research, LLC

DEVICE DESCRIPTION **807.92(a)(4)**

The Melys Atrial Fibrillation Monitor is a lightweight portable device for measuring and displaying heart irregularity and pulse rate. The device consists of the following – 1) Atrial Fibrillation Monitor, 2) Finger Sensor (K101692), 3) Power Supply and 4) Instruction Manual.

The Melys Atrial Fibrillation Monitor device receives physiological data relating to heart rhythm from a finger sensor (K101692) attached to the patient's finger. The device captures, processes and records this data. Once sufficient data has been captured the device will run a mathematical analysis on the data and presents an indicative result of the patient's likelihood of suffering from atrial fibrillation or other heart irregularity.

The monitor contains a rechargeable battery, and a power supply is provided with the monitor for charging the monitor's battery. The finger sensor is connected to the monitor and with the pressing of the start button is ready to deliver trace measurements within 10 seconds. Each measurement is shown in a large display with a light and a number (the Arrhythmia Index Result). A history results bar at the bottom of the monitor will show the results of the previous 8 analyses with each light indicating each separate result by a green, amber, or red light. In the upper right corner of the display is an indication of the input signal strength and the level of battery charge.

DEVICE INDICATIONS FOR USE **807.92(a)(5)**

The Melys Atrial Fibrillation Monitor is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

	Subject	Predicate	
Parameters	Melys AFS Ltd.	Lechnologies Research, Inc.	Similarities and Differences
510(k) Number		K052767	
Indications for Use	The Melys Atrial Fibrillation Monitor is indicated for self-testing by patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.	The AfibAlert™ is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.	Same
Regulation Name	Telephone electrocardiograph transmitter and receiver	Telephone electrocardiograph transmitter and receiver	Same
Product Code	DXH	DXH	Same
Intended User	Adult	Adult	Same
Prescription device for home use	yes	yes	Same
Single Patient Use	yes	yes	Same
Monitors regularity of heartbeat	yes	yes	Same
Alerts user to an irregularity in their pulse through a light indicator.	yes	yes	Same
Principle of Operation	The monitor passes light through the fingertip sensor and receives data from which the waveform is directly created. Displays regularity or irregularity with a light indicator.	The monitor creates an electrocardiograph reading from the data received from the thumb, wrist or chest sensor from which a waveform is derived. Displays regularity or irregularity with a light indicator.	The Melys monitor receives its information from the finger rather than the thumb, wrist or chest, using a familiar, pulse oximeter style finger sensor.
Device Design	Monitor obtains waveform via finger sensor and displays waveform in real time on the monitor with an arrhythmia index.	Cardiac event recorder with thumb, wrist, or chest sensor that displays results by light indicator (green, red), but no pulse	Different acquisition of waveform but same result and light indicator display of heart regularity or

	Light display (green, amber, or red) indicates heart regularity or irregularity. Last 8 tests are stored on the display by light indicator not Arrhythmia Index number.	waveform. Records, stores and transmits results over the telephone wire.	irregularity.
Functional Features			
User programmable	No	No	Same
Recording length	10 seconds (Recommended four (4) consecutive measurement should show same indication (red, amber or green) before a conclusion is drawn)	45 seconds	Melys Atrial Fibrillation Monitor Instructions recommends four (4) consecutive measurement should show same indication (red, amber or green) before a conclusion is drawn
Low battery detection	Yes	Yes	Same
Heart rate accuracy	± 1 BPM	± 1 BPM (average for data collected, updated every three (3) seconds)	Same
Physical and Environmental			
Weight (w. Batteries)	200g 7.05 oz.	4.6 oz.	Slight difference does not affect safety & efficacy
Size	4.52" x 4.13" x 1.37"	5.88" x 2.75" x 1.11"	Slight difference does not affect safety & efficacy
Operational Temperature	20°C to 40° C	0° C to +45° C (+32° F to 113°F)	Slight difference does not affect safety & efficacy
Storage & Transport	0-20°C	-120°C to +60°C (-4°F to 140°F)	Slight difference does not affect safety & efficacy
Power			
Battery type	Lithium-ion Polymer Battery (Minamoto) 3.7 V	Two (2) AAA 1.5 V Eveready x -92	Both use battery as power source
Battery Life	40 days continuous	90 days nominal used 1 x per day	Difference does not affect safety & efficacy
Differences			
Memory Capability	No	Yes	The subject device displays the last eight Indicator lights on the monitor face but not the arrhythmia Index.
Transmission of Data	No	Yes	The subject devices does not transmit data

Patient Interface	Finger Sensor	Thumb, or wrist sensor, and direct chest contact	Most users will have encountered a fingertip sensor such as the Melys AFS Ltd fingertip sensor and therefore require little instruction on how to correctly use it. The finger sensor passes light through the fingertip and creates a waveform from this data. The Lechnologies thumb, wrist and chest sensors require user education to use correctly. The chest sensor requires that the patient removes clothing and is therefore less convenient than a fingertip sensor.
Waveform display	Waveform shown in real time on the monitor screen.	Waveform is not shown on the monitor, but is available by a download-from the Lechnologies Research, Inc's website.	While the waveform is available to the user, the subject device is the only device with the display in real time.

NON-CLINICAL PERFORMANCE DATA **807.92(b)(1)**

Safety Testing
The Melys Atrial Fibrillation Monitor is compliant to the safety standards.
IEC 60601-1 (1988), 2nd Edition, Medical Electrical Equipment, Part 1: General Requirements for Safety +A1(91) + A2(95)

Comparative Test
A comparative test was conducted between the subject and predicate device. The Melys Atrial Fibrillation Monitor matched the predicate device in all tests, giving the same heart rate measurements and the same indications towards atrial fibrillation in all but Tests 9 and 10, where the Melys Atrial Fibrillation Monitor correctly indicated that no atrial fibrillation was present.

Human Factor Study
A Human Factor Study was performed with 20 volunteers to evaluate ease of use and label comprehension. There was a 100% agreement that the device was easy to use and the instructions were clear and understandable.

CLINICAL PERFORMANCE DATA **807.92(b)(2)**
Two clinical trials were conducted for verification and validation of Melys Atrial Fibrillation Monitor, safely and effectively identifying as having an arrhythmia those patients identified by EKG examination as having atrial fibrillation.

The Clinical Trial results show the EKG diagnosis compared with the Melys Atrial Fibrillation Monitor predictions.

CONCLUSION **807.92(b)(3)**
Electrical, mechanical and software testing was conducted and data collected in accordance with applicable standards to ensure that that the device performs in accordance with applicable standards to ensure that the device performs according to specification and to verify that the device is suitable for home use. A Human Factor Study was conducted to verify Ease of Use and Label Comprehension

Advanced Fluidics considers the Melys Atrial Fibrillation Monitor to be equivalent to the predicate device. This conclusion is based upon the devices' similarities in functional design, method of use for self-monitoring and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

Advanced Fluidics, LLC
c/o E J Smith
1468 Harwell Ave
Crofton, MD 21114 US

Re: K132206
Trade/Device Name: Melys Atrial Fibrillation Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Atrial Fibrillation Detector
Regulatory Class: Class II
Product Code: DXH
Dated: February 12, 2014
Received: February 14, 2014

Dear E J Smith,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

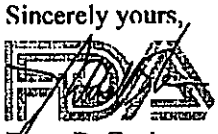
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free

number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132206

Device Name
Melys Atrial Fibrillation Monitor

Indications for Use *(Describe)*

The Melys Atrial Fibrillation Monitor is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Concur

Date: 2014.03.19 15:24:42 -04'00'

for Bram Zuckerman

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